OPTIONS FOR MITIGATING PERCUTANEOUS EXTENSION CONNECTOR MIGRATIONS Medtronic

The following instructions provide guidance on mitigating migration of the percutaneous extension connector into the tunneling track with the advanced evaluation.

Solution 1:

1. Using a 2-0 or smaller nonabsorbable suture, loop the suture around the percutaneous connector and percutaneous extension body (Figure 1)

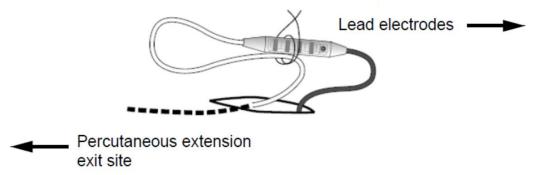


Figure 1. Suture looped twice around the percutaneous extension connector and extension body

2. Tighten and tie the suture securely around the percutaneous extension connector and extension body (Figure 2)

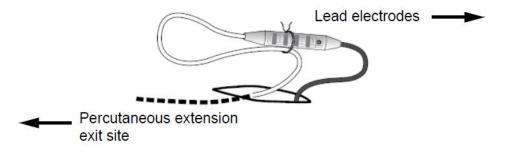


Figure 2. Suture secured and tied around the percutaneous extension connector and extension body.

3. Create a subcutaneous pocket above or below the incision that is perpendicular to the percutaneous extension tunneling path to place the percutaneous extension connector and strain relief loops (Figure 3 and 4).

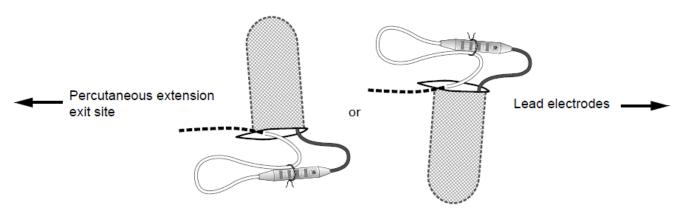


Figure 3. Enlarged image of the subcutaneous pocket above and below the incision for the percutaneous extension and strain relief loops.

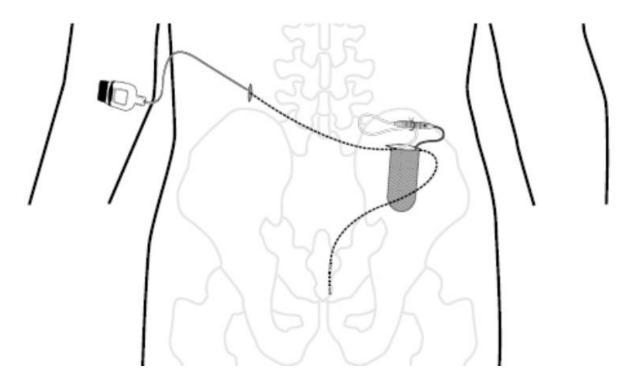


Figure 4. Subcutaneous pocket below the incision for the percutaneous extension and strain relief loops.

4. Rotate the percutaneous extension connector so the set screw block and lead are pointing down and insert the percutaneous extension connector and extension body into the pocket (Figure 5A & 5B).

Note. Position the lead and extension, avoiding sharp bends or kinks. Fluoroscopic observation may be necessary.

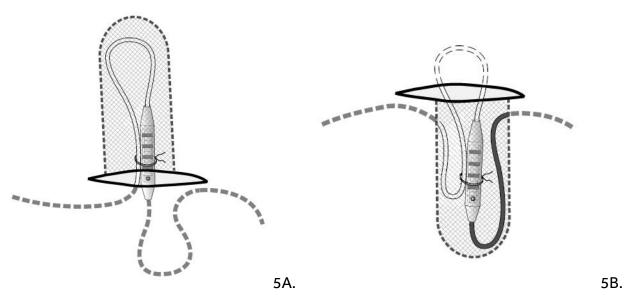


Figure 5A. shows the pocket above the incision. Figure 5B. shows the pocket below the incision.

Preparing for neurostimulator implant after advanced evaluation

- 1. Carefully open the percutaneous extension-lead connector site and expose the lead and connector.
- 2. Using the torque wrench, loosen the setscrew in the setscrew connector by turning the wrench counterclockwise.
- 3. Gently remove the lead from the lead connector end of the percutaneous extension.



Caution: If resistance is felt when removing the lead from the percutaneous extension, loosen the setscrew slightly to ensure that it clears the lead contacts. Avoid disengaging the setscrew. Inspect the lead contacts for damage (flattening or stretching of lead) if resistance was felt prior to removal. Damaging the lead may result in additional surgical steps.

4. Cut the percutaneous extension near the incision proximal to where it is tied to the connector (Figure 6).

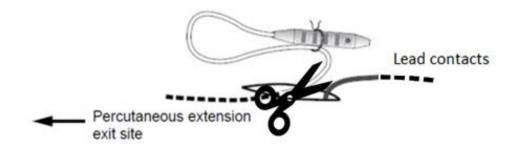


Figure 6. Image showing where to cut the percutaneous extension for removal.

- 5. Withdraw the remainder of the percutaneous extension through the contralateral exit site and discard it.
 - **Warning:** Ensure sterile field is maintained during removal of the percutaneous extension to minimize the risk of infection.
- **6.** Close the exit site and proceed to connecting the lead to the neurostimulator, refer to product literature packaged with the neurostimulator.

Solution 2:

1. With the tunneling tool in place and prior to pulling the percutaneous extension to the pocket site, place a resorbable suture in the tissue around the tunneling rod near the entry site from the pocket (Figure 1).



Figure 1. Suture placed around the tunneling rod in the subcutaneous tissue

Note: Include the superficial fascia when placing the suture in the tissues around the tunnel rod.

- 2. Retract the tunneling tool to pull the lead connector end of the percutaneous extension from the percutaneous extension exit site to the pocket site.
- **3.** Remove the percutaneous extension from the carrier tip.
- **4.** Secure the preplaced suture in the tissue around the percutaneous extension closing the tunneling path (Figure 2).

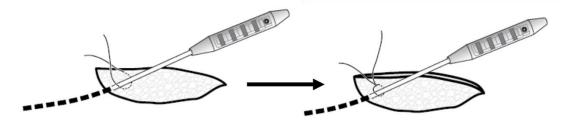


Figure 2. Securing the suture around the perc extension

Note: Do not overtighten the suture to avoid crushing the extension body.

5. Refer to the lead implant manual to compete the implant process.